

Appl No.: 10/064,859  
Amndt. Dated 10/20/04  
Reply to Office Action of 09/23/2004

### REMARKS

In response to the office action dated September 23, 2004, please enter the forgoing claims and consider the following remarks. Claims 1, 2, 4 through 12, 17 through 19, 23, 24, 35, 40, 42, and 45 have been amended. Claims 3, 13 through 16, 20, 21, 29, 43, and 44 have been cancelled. Claims 46 through 51 are new. Forty-one claims remain in the case. The independent claims are claims 1, 35, and 40, each of which has been amended.

This application is a continuation in part of co-pending application 09/797,325, and includes material to bar code readers and handling of data generated thereby. See Figures 6N and 6O and pages 75-80 of the specification. In view of the amended claims, which now all include limitations to barcode technology, none of the claims conflict with claims in co-pending application 09/797,325 and that objection to the claims on grounds of 37 CFR 1.78(b) should be withdrawn.

Applicants note the examiner's provisional obviousness double patenting rejection of certain claims. Although such a rejection is properly suspended pending the allowance of claims in the co-pending '325 case, applicants respectfully suggest that the amended claims patentably distinguish over the secondary references cited by the examiner, as will be shown below, and that this ground for rejection can also be withdrawn.

Original claims 35-39 were rejected under 35 U.S.C. 102(b) as being anticipated by Stacey et al. (US Patent 5,769,811). Claim 35 has been amended to point out the barcode data is assigned to at least one of a plurality of blood processing categories. Manipulation of the barcode data, as explained on pages 75-77 of the specification, and selective assignment to one of a plurality of categories is not shown or suggested in Stacey '811. The Stacey '811 apparatus uses a barcode to confirm the type of disposable mounted in the blood processing machine. Means for assigning the detected barcode data to one of several categories is not contemplated. New claims 49, 50 and 51, which depend from claim 35, also distinguish over the art. Stacey '811 does not show assigning a plurality of scanned barcode data to a selected category, or assigning a datum of the scanned barcode data to multiple categories, nor does Stacey suggest that the categories include comments or notes, anticoagulant, saline, donor identification, operator identification, laboratory identification, and storage solution. Original claims 36-39 should be allowed with their parent claim.

Similar limitations to the limitations of claims 35 and 49-51 with respect to the use of barcode data (explained above) have been included in claim 1 and in new

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dependant claims 46-48. Claims 46-48 and claim 1, together with claims 2,4-12, 17-19, 22-34, which depend from claim 1 should, therefore, be allowed.

Certain original claims of this application, including claims 17-19, and 22-32, have been rejected over Urdahl et al. (US Patent 5,658,240) in view of Gilcher et al. (US Patent 6,113,554). In particular, the examiner has suggested that Urdahl et al. does not specifically disclose the use of a database, and relies, in connection with certain claims, on Gilcher et al. (US Patent 6,113, 554), which uses the word "database", see, e.g., column 10, line 13. It is believed, however, Urdahl et al. in fact discloses a database of much the same type as that disclosed in Gilcher et al., as shown, for example, in Urdahl et al. column 15, lines 16-48. Data from or concerning the donor is collected and stored either for use in reports or for preparing a "standardized" procedure order for a particular donor. (See, e.g., column 15, lines 40-43.) Further, in column 23, lines 21-26, Urdahl et al. mentions that its optimization procedures are "... based upon maintaining one or more appropriate data bases [sic] of information ..." The disclosure further states that "[t]he central input station 148 which [sic] interacts with the one or more data bases [sic] and displays various information to the operator ..." The kind of database disclosed in Urdahl et al. (and in Gilcher et al.) is used to assemble data about the donor, either entered by keyboard or otherwise or developed by the operation of the blood processing machine.

In addition to the distinction of claim 1, it is believed that the present invention, as set forth in the amended claim 17, differs from the cited art. In the present system, not only is information about the donor compiled in the database, but information on the relative needs of the blood product facility (a hospital, blood bank, etc.) for different blood products is maintained and used to select both the collection procedure and the type of products collected from the donor. A particular donor may be able to most efficiently provide a particular combination of blood components, but if a second combination is needed, the second combination should be collected, even at the cost of efficiency. For example, the specification explains (page 20, lines 1-24):

"... The concept of optimization here generally refers to achieving the maximum or best product output depending upon certain circumstances (e.g., obtaining the most product in a certain specified time or achieving a specific yield in the fastest time). On the other hand, the concept of data manipulation is more generally here intended to have a similar yet less exacting connotation, such that perhaps the best or maximum output may, but will not necessarily be the result. Thus, data manipulation is here intended to encompass optimization calculations in addition to providing perhaps less than optimum but still high

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efficiency results depending on certain further combinations of criteria. Thus, data manipulation is intended to generate more and/or perhaps better options to the blood donation center. For example, blood centers may prefer or determine to require certain combinations of products from certain blood type donors 14 (see Fig. 1B); then the blood center 1000 can prioritize this in the computer/database 140 so that those donors will donate those combinations even if the particular yields or donation times are not fully optimized according to the concept of optimization set forth above. Thus, yield or time optimization can be made secondary to other data requirements and/or manipulations. Note also that optimization and/or manipulation may be performed without requiring the central system 140 to collect/retrieve data from the various apheresis assemblies 10. Thus, communications may be made only one-way to (or from) the apheresis assemblies 10. Further, a preferred purpose for performing the optimization and/or manipulation functions centrally is to allow selection of the donation procedure prior to connection of a donor to a machine 10; thus, a particular product or products and the corresponding tubing set (if there are distinctive such sets) may be selected prior to machine set-up and donor connection. Also it could prove that the donor may not be able to provide a useful donation (for the end recipient/patient 15; see Fig. 1B), and this could thus be determined prior to machine set-up and/or donor connection." [Emphasis added.]

See also, Fig. 3D and page 47, lines 3-12 and pages 49-50. This application teaches that blood component collection should be controlled not only for optimal production of blood components from the particular donor, as taught by Urdahl, et al., but also for blood components needed by the blood product facility. Collection of blood components that are unlikely to be used wastes the resources of the donor and the blood collection facility, however "efficient" or "optimal" the collection process may be. This concept is incorporated in amended independent claims 17 and in dependant claims 18, 19, 22-28, and 30-32. It is respectfully submitted that Urdahl et al., either alone or in combination with Gilcher et al., does not teach a module for collecting need data concerning need for selected blood products nor a module for selecting an extracorporeal blood processing procedure based on manipulated donor data and need data (Claim 17). Claims 17 and its dependant claims should also be allowed for this reason.

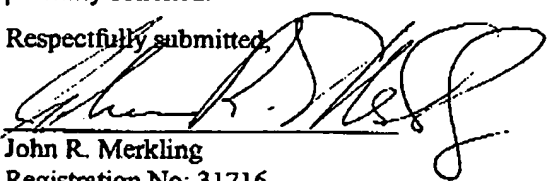
Claim 40, as amended, distinguishes over Stacey '811 as explained in connection with claim 35 above and also over Urdahl '240 and Gilcher '554. Urdahl '240 and Gilcher '554 do not teach a central database containing information concerning demand for selected blood products nor generating preparation data based, at least in part, on information concerning demand for selected blood products. Nor do these references teach assigning barcode data to a plurality of categories (Amended claim 42). It is respectfully suggested that these claims are in condition for allowance, as are claims 41 and 45, which depend from claim 40.

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The claims, as amended, are believed to be in condition for allowance, and the examiner's reconsideration of the claims is respectfully solicited.

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Date

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